UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, PIRELLI ARMSTRONG RETIREE MEDICAL BENEFITS TRUST; TEAMSTERS HEALTH & WELFARE FUND OF PHILADELPHIA AND VICINITY; PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, and DISTRICT 37, AFSCME-HEALTH AND SECURITY PLAN; JUNE SWAN; BERNARD GORTER, SHELLY CAMPBELL and CONSTANCE JORDAN	:	
Plaintiffs,	:	C.A. No. 1:05-CV-11148-PBS
v.	:	
FIRST DATABANK, INC., a Missouri Corporation; and McKESSON CORPORATION, a Delaware corporation,	:	
Defendants.	:	
DISTRICT COUNCIL 37 HEALTH AND SECURITY PLAN, on behalf of itself and all others similarly situated,	:	
Plaintiff,	:	C.A. No. 1:07-CV-10988-PBS
v.	:	
MEDI-SPAN, a division of WOLTERS KLUWER HEALTH, INC.,	:	**LEAVE TO FILE GRANTED**
Defendant.	:	**ON DECEMBER 20, 2007**

OPPOSITION TO THE PROPOSED FDB AND MEDI-SPAN SETTLEMENTS BY PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION AS *AMICUS CURIAE*

Pursuant to this Court's Order of August 21, 2007, the Pharmaceutical Care Management Association ("PCMA"), as *amicus curiae*, submits this opposition to the proposed settlements (the "Proposed Settlements") between the Plaintiffs in the above-captioned cases and Defendants First Databank ("FDB") and Medi-Span (FDB and Medi-Span are herein the "Settling Defendants"). PCMA also respectfully requests to be heard at the Fairness Hearing now scheduled for January 22, 2008 at 2:00 p.m. to answer any questions the Court may have concerning its objections.

PRELIMINARY STATEMENT

For no contribution whatsoever by either of them, and with little or no disruption to their respective businesses or those of their respective parent corporations – Hearst Corporation ("Hearst") and Wolters Kluwer Health ("Wolters Kluwer") – the Settling Defendants, as well as Hearst and Wolters Kluwer, stand to receive – if the Proposed Settlements are approved – a release of all claims against them, while offloading responsibility for their conduct onto parties that this Court has specifically identified as having had no involvement in the Settling Defendants' alleged scheme, including the pharmacy benefit management industry that PCMA represents. *See*, *e.g.*, Trans. of May 22, 2007 Hearing at 9, 12-14.

Instead, by arbitrarily lowering the Average Wholesale Price for over 8,000 National Drug Codes ("NDCs") – which Plaintiffs' counsel admits is "more than five times the number of drugs at issue in the litigation effort itself"[1] – including approximately 7,000 NDCs that are not

[1] Class Plaintiffs' Memo. of Law in Support of Motion for Preliminary Approval of Proposed Medi-Span Settlement, Certification of Settlement Class and Approval of Notice Plan, Doc. #3, at 8 (5/25/07); *see also* Class Plaintiffs' Memo. of Law in Support of Jt. Motion for Prelim. Approval of Proposed First Databank Class Settlement, Certification of Settlement Class and Approval of Notice Plan, Doc. #119, at 10 (10/4/06).

even alleged to have been implicated in the Settling Defendants' scheme,[2] the Proposed Settlements aim to disrupt the entire pharmaceutical marketplace. They purport to bind – and to grant releases on behalf of – some 40,000 Third Party Payors ("TPPs"). They would affect the interests of millions of consumers. They would also necessarily impact every entity in the wholesale and retail pharmaceutical distribution chain, including tens of thousands of retail pharmacies (including both large chains as well as individual and family-owned independent pharmacies), every pharmacy benefit manager ("PBM") in the country, and hundreds of thousands of health benefit plans, self-insured employers, third-party administrators ("TPAs") and union-sponsored health plans.

Furthermore, although they impact the entire pharmaceutical marketplace, the Proposed Settlements would – if approved – be implemented without any legislation, regulation, findings of fact, cost-benefit analysis or administrative process. As this Court knows better than any, and as the Plaintiffs themselves concede, "[t]he private (and public) pharmaceutical reimbursement systems have at their core critical dependence upon accurate and timely publication of the current AWP for every active formulation of drugs dispensed by retail pharmacies." SAC, Doc. #174, at ¶ 78. Yet the Proposed Settlements would abruptly and arbitrarily change the AWP for nearly every branded prescription NDC in America – even though the prices of the vast majority of these NDCs are not alleged to have been inflated by the Defendants' conduct.[3] Apart from

[2] *See* Second Amended Class Action Complaint ("SAC"), Doc. #174, at ¶ 9 ("McKesson and First Data, without any economic justification, raised the WAC-to-AWP spread to 25% *for over four hundred brand-name drugs* that previously had received only the 20% markup amount.") (emphasis added).

[3] Oddly, in their briefs and before this Court, the Plaintiffs trumpet the fact that the Proposed Settlements sweep far more broadly – and, in particular, affect far more NDCs – than the alleged injury caused by the Settling Defendants' scheme. *See* Class Plaintiffs' Memo. of Law in Support of Jt. Motion for Prelim. Approval of Proposed First Databank Class Settlement, Certification of Settlement Class and Approval of Notice Plan, Doc. #119, at 10 (10/4/06) ("FDB has agreed to rollback from about 1.25 to 1.20 the markup factor for 8,487 formulations of drugs. The provisions of the Settlement, therefore, apply to more NDCs than set forth in the FAC (the rollback applies to 8,487 NDCs while the FAC relates to 1,659 NDCs). …

their obvious over-breadth, the Proposed Settlements entail the sort of industry-wide rate-setting that is ordinarily the domain of legislation or administrative regulation. Such efforts are, moreover, ordinarily informed by extensive study and expert analysis, none of which has been undertaken in this case. Indeed, in June of this year the Court proposed the selection of an independent economic expert to advise the Court on the fairness of the Proposed Settlements. *See* Trans. of June 21, 2007 Hearing at 26, 30-31. Yet as of December 19, 2007, no expert has been appointed and no study of the myriad and complex economic and public policy issues raised by the Proposed Settlements has been commenced, let alone concluded.

The Proposed Settlements should be rejected for three independently sufficient reasons. First, they fail on the most important measure of fairness; they fail to confer *any benefit* on a critical class of purported beneficiaries – individual consumers. *See generally E. Tex. Motor Freight Sys. Inc.* v. *Rodriguez*, 431 U.S. 395, 405 (1977). The only clear beneficiaries of the Proposed Settlements are the Settling Defendants – FDB and Medi-Span. As this Court has repeatedly noted, the Settling Defendants would pay nothing in the Proposed Settlements and yet would receive general releases of claims against them. *See, e.g.,* Trans. of Oct. 24, 2006 Hearing at 15 ("It's rare that I see a proposed settlement where not a penny exchanges hands."). Second, the inflation in AWP that the Proposed Settlements seek to remedy is a non-existent problem. As the Court has already recognized by placing a limit on the length of the Class Period, any inflation in AWP caused by the alleged scheme has already been accounted for by sophisticated

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[T]he drug coverage represented by the settlement is in excess of 95% of the retail branded drug transactions in the United States."); Trans. of May 22, 2007 Hearing at 50 ("First Databank would effectuate a rollback from .25 to .20 of every drug in its database that was on a markup factor basis. So that would be far more than the drugs that were actually the subject of the litigation. Essentially all branded drugs that are on a markup basis would be rolled back."). Evidently lost on Plaintiffs is the fact that they are supposed to be pursing a civil action for redress of a specific injury. Instead, Plaintiffs act more like legislative or administrative policymakers who have been elected or appointed to make policy with respect to pharmaceutical pricing and reimbursement.

TPPs, their PBMs, and other market participants. If most Plaintiffs are not entitled to recover damages up to the present time – as the Court has already suggested – it necessarily follows that there is no current AWP inflation that must be remedied by an across-the-board "rollback" of AWP. Third, the Proposed Settlements, by design, seek to disrupt the pharmaceutical distribution chain and impose costs on parties who are not even alleged to have participated in the Settling Defendants' scheme.

The Proposed Settlements are manifestly unfair and inadequate and should be rejected.

BACKGROUND

PCMA is the national association representing America's PBMs, which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.[4] It has previously voiced objections to the then-proposed Settlement with FDB in a letter to the Court dated June 20, 2007, a copy of which is attached hereto as **Exhibit 1** for the Court's convenience.

The Settling Defendants will pay nothing in the Proposed Settlement and instead have agreed to make sweeping changes to AWP – the pricing benchmark for thousands of contracts between PBMs and their clients, on the one hand, and PBMs and retail pharmacies, on the other hand. Despite allegations that they engaged in a RICO conspiracy to inflate AWP, the Settling Defendants will not make any monetary payment to or for the benefit of the members of the

[4] PCMA's members include the following PBMs: Aetna Inc.; Caremark Inc., a wholly owned subsidiary of CVS/Caremark Corporation; CIGNA Health Corporation; Express Scripts, Inc.; Medco Health Solutions, Inc.; RxSolutions, Inc. d/b/a Prescription Solutions, a wholly owned subsidiary of PacifiCare Health Systems, LLC, which in turn is a wholly owned subsidiary of UnitedHealth Group Incorporated; Wellpoint Pharmacy Management (a d/b/a for Professional Claims Services, Inc.) and Anthem Prescription Management, LLC, both of which are wholly owned subsidiaries of Wellpoint, Inc.; US Scripts, Inc.; Scriptrax, part of Novant Health – a not-for-profit healthcare system.

Plaintiff Classes under the Proposed Settlements. *See* SAC, Doc. #174, at ¶¶ 165-94. Instead, the Settling Defendants have agreed to make a number of sweeping and arbitrary changes to the core prescription drug pricing benchmark – AWP – for all branded prescription drugs. In exchange for the changes they will make to AWP, the Settling Defendants and their wealthy parent companies, Hearst and Wolters Kluwer, stand to receive general releases of liability from the Plaintiff Classes.[5]

Under the terms of the Proposed Settlements, the Settling Defendants have agreed to effectuate an artificial reduction in AWP for over 8,000 NDCs. The Complaints against them had alleged that "over four hundred brand-name drugs" were implicated in the Settling Defendants' alleged scheme, *see* SAC, Doc. #174 at ¶ 9. In their settlement motion papers, Plaintiffs claim that approximately 1,600 NDCs were affected by the scheme. *See supra* note 1. Yet, the Proposed Settlements would roll back AWP for approximately 7,000 additional NDCs that are not alleged to have been implicated in the scheme. *Id.* The Plaintiffs concede this. *Id.* The Settling Defendants have also agreed that they will discontinue publishing the AWP and BBAWP fields for all pharmaceuticals within 2 years (for FDB) or 3 years (for Medi-Span) from the effective date of the Settlements. In addition Plaintiffs have agreed to establish a "Data Room" accessible to Plaintiffs' counsel for use in other pharmaceutical pricing and reimbursement litigation.

Because of the potentially sweeping effect that the Proposed Settlements would have on the prescription drug marketplace, this Court noted during the hearing held on June 21, 2007 that it would be valuable to have an independent expert perform an economic analysis of the

[5] Since FDB and Medi-Span could, as a practical matter, effect this rollback absent any settlement, presumably their willingness to do so in the context of the Proposed Settlements is contingent on the Settling Defendants – and their parents – receiving a class-wide release from liability for implementing the rollback.

Proposed Settlements. *See* Trans. of June 21, 2007 Hearing at 30 (advising that the parties should "have an independent person looking at it because it will have such enormous ramifications for the nation"). In the ensuing six months, the parties apparently have failed to engage this Court's suggestion of an independent economic analysis. The Proposed Settlements – if implemented – will occur without the benefit of any such independent analysis.

ARGUMENT

I. MOST CONSUMERS WILL NOT BENEFIT FROM THE PROPOSED SETTLEMENTS

The Proposed Settlements confer no meaningful benefit on individual consumers. As one District Court in this Circuit recently noted, "it is the responsibility of Plaintiffs' counsel to ensure that the settlement *provides real value* . . . to their . . . clients." *Sylvester v. CIGNA Corp.*, 369 F. Supp. 2d 34, 49 (D. Me. 2005) (emphasis added). And, in the context of a proposed class settlement, it is the responsibility of the Court to ensure that that has happened. Yet the Consumers included in Class 1 – namely those who paid a percentage co-pay for branded drugs for liability and damages over a 3 ½ year period – will not receive "real value" from the Proposed Settlements for the following reasons:

First, the Proposed Settlements involve no compensation to the Consumer Class, as in the typical class action settlement, only a supposed “rollback” of AWP. Despite the fact that the Consumer Class is explicitly "certified for liability and for damages," Order of Aug. 27, 2007, Doc. #317, at 2, the Proposed Settlements include no monetary payment to the Consumer Class. Instead, they provide only injunctive relief. *See* Settlement and Release at (A), Doc. #120, at 19-20. As such, the Proposed Settlements stand in sharp contrast to two recent settlements in the pharmaceutical field: (1) *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516, 539 n.18 (3d

Cir. 2004), where "every consumer who filed a claim on or before April 30, 2003, *will receive 100% of their Recognized Loss*" (emphasis added); and (2) *In re Lupron Marketing and Sales Practices Litigation*, 228 F.R.D. 75, 86-87 n. 22, n. 24 (D. Mass. 2005), where the total amount allocated between the two settlement agreements was $150 million, with "consumer-purchasers" being entitled to recover 30% of their total out-of-pocket payments for Lupron, or $100, whichever was larger, to the extent of the pool. Unlike the settlements in *Warfarin* and *Lupron*, and countless other class settlements, the Proposed Settlements will confer no benefit on individual Class members whose claims are effectively being released. *See, e.g.*, Trans. of June 21, 2007 Hearing at 14 (noting that "with respect to consumers, now, they're the ones who are not getting a penny and are not likely, many of them, to benefit").

Second, even if some subset of the Consumer Class might somehow extract some minimal benefits from the Proposed Settlements, those benefits would not be "fairly distributed . . . in accordance with objective criteria" or "rationally based on objective differences in the positions of the Class members," as this Court's precedents require. *Bussie v. Allmerica Fin. Corp.*, 50 F. Supp. 2d 59, 75-76 (D. Mass. 1999). Rather, as explained below, the benefits would be distributed irrationally and inequitably, offering no remedy to many Consumer Class members whose health conditions or insurance plans have changed in the intervening years, while at the same time rewarding many other consumers who are not even alleged to have been harmed. This is precisely the sort of class conflict that the First Circuit has deemed unacceptable. *See, e.g., Duhaime v. John Hancock Mut. Life Ins. Co.*, 183 F.3d 1, 5 (1st Cir. 1999) (stating that "different recoveries for similarly harmed persons . . . can constitute powerful evidence that a fiduciary obligation has not been honored" and that "courts should 'withhold approval from any settlement that creates conflicts among the class'") (quoting *In re Gen. Motors*

Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 809 (3d Cir. 1995)); *City P'ship Co. v. Atl. Acquisition L.P.*, 100 F.3d 1041, 1044 (1st Cir. 1996) (noting that "[t]he presence of a conflict of interest would render the settlement suspect").

The Notice to consumers carefully circumscribes the Consumer Class as those who purchased, via co-insurance, from January 1, 2000 to the date of the final settlement approval, those prescription drugs identified on the list of drugs for which FDB reported prices, or who purchased from December 19, 2001 drugs on the list for which Medi-Span reported prices.[6] Assuming, for the sake of argument, that this were a well-tailored definition of those consumers harmed by the Defendants' alleged conspiracy to inflate AWP, then presumably the benefits (if any) from the Proposed Settlements' corresponding reduction in AWP would accrue only to consumers who not only still purchase prescription drugs, but who also do so through a co-insurance arrangement with their health plan. But given the constantly changing nature of individual health conditions, health plans, benefit structures, and the pharmaceutical marketplace as a whole, it is likely that many Consumer Class members no longer purchase the identified drugs or do not purchase them by means of a co-insurance arrangement with their health plan. For these individuals, there will be no benefit from the Proposed Settlements, even under the Plaintiffs' rosy projections.[7] As this Court aptly put it, "consumers in the past sometimes may have never used the drug again," and "[s]o essentially there's a whole cohort of people ... who

[6] *See* Attachments to Declaration of Katherine Kinsella Regarding Changes to the Joint Notice Program.

[7] Plaintiffs incorrectly contend that the problem of how to assure protection for those Consumers who have "limited need to purchase prescription pharmaceuticals in the future" can be solved simply by the "mandatory notice and opt-out rights provided under Rule 23(b)(3)." Supp. Memo. of Law in Further Support of Jt. Motion for Prelim. Approval of Proposed Settlement, Doc. #172, at 1 (11/22/06). This is counter-intuitive and at odds with the fundamental rationale for class actions and settlements – namely, to *compensate* plaintiffs with claims too small to pursue individually. Indeed, how it is that a class action settlement can both supposedly "protect consumers and . . . create an incentive for them to submit claims," while also forcing the most vulnerable Consumer Class members to opt out and take their relatively small claims to further litigation, is nowhere explained. *See Warfarin*, 391 F.3d at 539.

essentially won't get relief from what they overpaid in the past." Trans. of Oct. 24, 2006 Hearing at 23.

Whereas some Consumer Class members would receive no recompense, other consumers *outside of the class* would find themselves in a much better position to extract the benefits (if any) produced by the Proposed Settlements. The rollback of AWP would apply across the board to all consumers going forward, regardless of whether they were affected by the alleged scheme in the past, and to approximately 7,000 more NDCs than are alleged to have been implicated in the alleged scheme. In fact, the Proposed Settlements purportedly cover some generic drugs,[8] even though it appears that consumers who bought generics are *excluded* from the Class, because the Proposed Settlements define "Marked-Up Drugs" as only "brand-name, self-administered drugs sold through retail pharmacies, including mail order." Order of Aug. 27, 2007, Doc. #317, at 2. Thus, many consumers who never even bought the allegedly impacted drugs – let alone via co-insurance and during the class period – and whose future purchases are limited to the "extra" NDCs that are not alleged to have been impacted by the Defendants' conspiracy, will nevertheless benefit from the Proposed Settlements. In contrast, Consumers who fall squarely within the Class, but whose circumstances have changed such that they are not purchasing prescription drugs at all or in the same amounts or under the same contractual arrangements, will not benefit at all. As this Court noted, "It's basically shifting from one class of people who may have been injured to a future class, the benefits, and so it's very unusual . . ." Trans. of May 22, 2007 Hearing at 58; *see also* Trans. of June 21, 2007 Hearing at 14 (noting that "[w]e're giving a benefit to a future class from the past"). It is impossible to defend this haphazard distribution as

[8] *See also* Settlement Website, *www.fdbmedispansettlement.com/fdbmedispan/drugs.htm* (last accessed Dec. 13, 2007), which appears to contain the list of drugs for which FDB will adjust its report by reducing the mark-up factor, including generics such as acetic acid, ampicillin, azithromycine, and ciprofloxacin.

being "rationally based on objective differences in the positions of the Class members" as required for approval of a class settlement. *Bussie*, 50 F. Supp. 2d at 76.

II. THE PROPOSED SETTLEMENTS ADDRESS AN ISSUE THAT HAS BEEN RESOLVED BY THE MARKETPLACE

The Proposed Settlements attempt to address an economic imbalance that has already been corrected by the pharmaceutical marketplace, which as this Court knows from its involvement in the underlying AWP litigation is both dynamic and vigorously competitive (an assessment shared by the FTC and the U.S. Department of Justice).[9] Pricing in this marketplace involves what the Congressional Budget Office calls "a complex set of market transactions involving prices, discounts, and rebates," with prices varying depending "upon the degree of competition in a marketplace and on purchasers' bargaining power." CBO, "Prescription Drug Pricing in the Private Sector," Jan. 2007 at 1. Purchasers of pharmaceuticals, including sophisticated PBM clients such as health plans and TPAs, not only have numerous choices among the many PBMs operating in the country, but also possess the ability – and enormous incentives – to bargain extensively for contractual provisions regarding the various discounts, rebates, fees and reimbursement formulas available.

The PBMs represented here by PCMA play a critical – and real-time – role in this competitive marketplace. Indeed, PBM contracts often contain terms that allow pricing factors to be adjusted during the term of the particular contract. Even if those terms are absent, as a practical matter, clients are nonetheless able to obtain pricing concessions in response to market developments in many instances. This Court itself has recognized the "huge amount of

[9] Federal Trade Commission and U.S. Department of Justice, "Improving Health Care: A Dose of Competition," ch. 7, at 15 (July 2004), available at www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf. See also Statement of the FTC, In re Caremark Rx., Inc../AdvancePCS, File No. 0310239 (Feb. 11, 2004), available at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf.

knowledge and leverage to do push back" that PBMs, as well as their clients and consultants, possess, which inevitably and continually result in pricing "adjustments."[10] Over time, as AWPs rose, the negotiated discounts deepened[11] for all Class members, whether TPPs or Consumers, through (1) increasingly deeper discounts in the mail service and retail channels, (2) lower administrative and dispensing fees, and (3) higher levels of manufacturer rebate sharing.[12]

This Court itself succinctly recognized that the marketplace for pharmaceuticals has already reacted to the allegedly higher AWPs, spearheaded by what it calls the "800-pound gorillas of pharmaceutical reimbursement" – PBMs. Order of Aug. 27, 2007, Doc. #317, at 4. For example:

> While there is no evidence that PBMs knew about the collusion to increase the WAC/AWP markup, PBMs are highly sophisticated entities, and the record supports defendant's [McKesson's] contention that they knew about the dramatic bump in AWP pricing in 2002 and had the power and financial incentive to institute *contract pricing mechanisms with pharmacies to bring reimbursement costs back to the status quo for client TPPs.* It was just a matter of time. *Id.* at 19 (emphasis added).

In sum, the marketplace has already adjusted substantially, if not entirely, for increases in AWP occurring in 2002 and 2003. Thus, the Proposed Settlements do not satisfy the repeated admonition from courts in this Circuit that class-action settlements must "fairly reflect the reality of the business situation presented by [the] lawsuit." *Bussie*, 50 F. Supp. 2d at 76 (quoting *M.*

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[10] "As we all know, the PBMs and the consulting contracts all give a huge amount of knowledge and leverage to do push back. So within a year or two of the bump-up of the price, you've already seen adjustments." Trans. of May 22, 2007 Hearing at 8, lines 6-10.

[11] *See, e.g.*, Expert Report of Robert D. Willig, Table 2 at 40, showing increasing discounts in the Class Period both at retail and at mail, and based on The Prescription Drug Benefit Cost and Plan Design Survey Report (2005).

[12] Even the Plaintiffs' former industry expert, Susan Hayes, agreed with this point and conceded that TPPs as a group were able to obtain greater discounts throughout the class period in response to higher AWPs.

Berenson Co. v. Faneuil Hall Marketplace, Inc., 671 F. Supp. 819, 824 (D. Mass. 1987)) (alteration omitted). Instead, the Proposed Settlements are completely at odds with economic reality.

Recognizing the dynamic nature of pricing in the pharmaceutical marketplace, this Court's Order of August 27, 2007 makes clear that Class 2 must be parsed "to include only those TPPs which had contracts based on AWP before the start of the scheme," and to exclude "any damages for drug reimbursements for drugs under contract, renegotiated or amended during the class period to provide price adjustments." Order of August 27, 2007, Doc. #317, at 18. This Class definition was crafted precisely in recognition of the fact that nearly all TPPs have renegotiated or amended their contracts with PBMs since 2002 (indeed, that is exactly how the market has adjusted to the 2002 and 2003 price increases), and there is therefore little-to-nothing left to the alleged AWP inflation at this late date. Yet, narrowing the Class in this manner does nothing to limit the broad impact that the AWP "rollback" would have on the pharmaceutical marketplace, in terms of administrative and transactional burdens. Indeed, the Court's clear resolve to limit the Class Period, on the grounds that the marketplace has already adjusted to any inflation in AWP, is completely at odds with *the* fundamental premise of the Proposed Settlements – namely, that the AWP inflation exists today, in substantially the same form as it did in 2002, and it must be "rolled back" through the reduction of AWP for all (or virtually all) branded prescription drugs in America.

In sum, as this Court has already well recognized, the Proposed Settlements aim to "roll-back" an AWP inflation that no longer exists.

III. THE PROPOSED SETTLEMENTS IMPOSE TREMENDOUS BURDENS ON PBMS AND THEIR TPP CLIENTS

This Court has commented more than once on the intense interest in the Proposed Settlements, *see, e.g.*, Trans. of May 22, 2007 Hearing at 58, and that intense interest is warranted, as they create uncertainty in a pharmaceutical marketplace that has relied on AWP as a benchmark, only to see it precipitously and substantially altered. The impact of the Proposed Settlements would extend far beyond the litigating parties. As this Court well knows, and as the Plaintiffs themselves concede, "[t]he private (and public) pharmaceutical reimbursement systems have at their core critical dependence upon accurate and timely publication of the current AWP for every active formulation of drugs dispensed by retail pharmacies." SAC, Doc. #174, at ¶ 78. PBMs have already been adversely impacted by the Proposed Settlements even before they have gone into effect. PBMs have incurred significant costs to address both customer and internal concerns regarding the terms of the Proposed Settlements on two fronts: First, they must determine which of their contracts are themselves included in the definition of the TPP class, since many PBM contracts are not included. Second, and even more critically, each time the AWP arbitrarily changes, PBMs are forced to determine how to modify or alter prices in their existing contracts, which is a costly and complicated process that must be tailored to each individual contract.

The First Circuit has long recognized that "the burden is placed squarely on the proponents of the settlement to show that it is in *the best interests of all those who will be affected* by it," including innocent third parties. *Greenspun v. Bogan*, 492 F.2d 375, 378 (1st Cir. 1974) (emphasis added); *see also Rolland v. Cellucci*, 191 F.R.D. 3, 13 (D. Mass. 2000) (listing "the possible effect of the Settlement Agreement on third parties" as a factor to be considered at the fairness hearing). Such a showing clearly cannot be made in this case. There is no way to argue that the Proposed Settlements would be in the best interests of the PBMs, who are not

alleged to have been involved in the Settling Defendants' scheme. They are not even in the best interests of the PBMs' TPP customers and retail pharmacy contracted partners. Because the main burdens imposed by the Proposed Settlements would fall upon innocent third parties, the Settlements cannot be approved as fair.

A. Determining Who's In and Out of the Class

PBMs are struggling, along with their TPP customers and their retail pharmacy contracted partners, to find answers to questions regarding the implications of these Proposed Settlements, including whether to opt out of the Class. This is not a simple determination. First, PBMs as a whole are excluded from the TPP Class, but some PBM contracts are included where the PBM is either "the fiduciary of the Third Party Payors" or "assumed, in whole or in part, the insurance risk of that prescription pharmaceutical benefit." This requires a relationship-by-relationship review of *every PBM contract with every client.* The reason is that PBMs do not generally assume "fiduciary" status for their external customers, but may act as "fiduciaries" in certain circumstances: (1) for their own employee benefit plans in administering prescription drug benefits, and (2) for those customers for which they agree by contract to assume limited "fiduciary" responsibilities (for claims appeals).

Even if a PBM undertakes a costly and lengthy review of all of its thousands of contracts to ascertain the Class inclusion question, it still has to contend with other anomalies of the Class definition that would result in differential treatment of similarly situated PBMs. For example, the definition of the TPP Class is internally inconsistent since it treats PBMs that are affiliated with health plans and insurers differently from stand-alone PBMs. A parent health insurer that has a subsidiary or affiliated PBM is included in the TPP Class, but the affiliated PBM itself may not be, except as to certain contracts that meet the "fiduciary" conditions specified above. For

another example, PBMs are treated differently from health insurers, since insurers are included in the Class without the "fiduciary" exceptions created specifically for PBMs. Again, the result is anomalous: the definition appears to include in the Class even TPAs that receive administrative fees for performing services for a benefit plan without bearing any "insurance risk." As mentioned earlier, the First Circuit has made clear that differential treatment of those in similar situations is inappropriate and that "courts should 'withhold approval from any settlement that creates conflicts among the class.'" *Duhaime*, 183 F.3d at 5 (quoting *In re General Motors*, 55 F.3d at 809).

B. Determining Proper Contractual Pricing for TPP Customers

PBMs are already fielding questions and concerns from TPP customers regarding how the Proposed Settlements would affect their particular contracts. As this Court has recognized, these contracts are highly customized, varying widely as to multiple terms, including the share of drug costs the client desires its members to assume, as well as payment terms and other conditions. PBMs and their customers bargain for how the contract will be priced, including the amount of administrative fees charged or the amount of risk a PBM and its client are willing to assume. Thus, if a PBM has to ascertain what a particular TPP client pays for various products both before and after the Proposed Settlements take effect, it has to perform calculations with respect to *each client.* There is a technological cost to the rollback of AWP embedded in the Proposed Settlements, which require nothing less than a *recalculation of pricing for most of the contracts PBMs have with their customers*.[13]

[13] These recalculations may require the alteration of systems to create an algorithm to assure the "correct" AWP has been applied to payments that have already been made, and may require adjustments even in the middle of the contract terms. Even for PBMs' sophisticated technological systems, these recalculations would pose a formidable challenge.

C. Determining Proper Contractual Pricing for Retail Pharmacies

As with TPP customers' contracts, there is no such thing as a "typical" payment rate to a retail pharmacy. Thus, a retail pharmacy contract for a single-source brand-name drug could provide for AWP minus 14% or some other percentage, with a dispensing fee that could amount to $2 or more, varying considerably. Again, the result is that the pricing alterations may have to be done on a case-by-case basis for the tens of thousands of retail pharmacies (both chains and independents) in any single PBM's network, which in many cases might involve the creation of new finance and underwriting models, again at additional expense to the PBM and to the retail pharmacy.

Most critically, if the AWP rollback prompted pharmacies to attempt to pressure PBMs to ensure that the economics of their current agreements remain in place (i.e., that the reimbursement to the pharmacy in dollar terms is the same both before and after the Settlements), the administrative costs of such adjustments would be enormous. Pharmacies in turn would themselves be under pressure to "reimburse" customers for the reported increase in AWP. There is also the possibility that certain pharmacies could suffer a negative financial impact from such a rollback, and that impact could be enough to result in some refusals to service consumer purchasers of prescription drugs, which would make the Proposed Settlements even harsher toward consumers.

IV. THE TERMS OF THE PROPOSED SETTLEMENTS ARE INAPPROPRIATELY CONDITIONAL, UNCERTAIN, AND UNWORKABLE IN PRACTICE

Rather than bringing certainty and finality to the pharmaceutical marketplace, the Proposed Settlements have brought much instability and uncertainty regarding how and when

they will be implemented, if and when they will be blown up, and what will happen in the inevitably frantic period in between.

A. The Conditional Nature of the Proposed Settlements Threatens to Create Further Difficulties for PBMs

PCMA objects vigorously to the ability of Plaintiffs' counsel and the Settling Defendants to "own the keys to the kingdom," so to speak, and be able to blow up the Settlements under certain conditions even *after* requiring PBMs and others to assume the costs and administrative burdens of ascertaining Class membership and implementing the pricing terms of the Proposed Settlements. If this happens, PBMs and others will be forced to adapt for a *third* time to the Settling Defendants' price tinkering. PCMA believes it is difficult to reconcile what the First Circuit insists is Plaintiffs' counsel's fiduciary duty to all Class members (*see Duhaime,* 183 F.2d at 4) with their ability to drive the Proposed Settlements, at least to date, in exactly the direction they want, and to maintain – even after the passage of considerable time – *the ability to unilaterally terminate them*.

First, the Settling Parties can make a determination to terminate the Proposed Settlements if "the number or identity of TPP Class Members who request exclusion from the class is unsatisfactory . . ." Agreement at 17. Plaintiffs' counsel has represented to the Court that, based on discussions with "five to ten large managed care organizations," counsel believes those five to ten managed care organizations will accede to the Proposed Settlements. Trans. of May 22, 2007 Hearing. But anecdotal accounts of the support of "five to ten managed care organizations" are not adequate to assure the marketplace that the Proposed Settlements will, indeed, go into effect or that they will not be terminated at a future date at the lead Plaintiff's whim – and after countless market participants have made yet another adjustment to AWP changes. Some of the PBMs, represented here through their association PCMA, are themselves affiliated with what

Plaintiffs' counsel terms these "large managed care organizations," and those organizations are seriously concerned about the potential for disruption to their patient relationships as well as their retail pharmacy relationships posed by the Proposed Settlements.

Second, there is another huge loophole in the Proposed Settlements: the so-called "Red Book" loophole. The "Red Book" loophole affords the Settling Defendants the ability to blow up the Settlements if a competitor enters the market.[14] Such a competitor could be Red Book or a number of other companies that discern a business opportunity in this area. It is therefore possible that, after the Settling Defendants' actions have caused PBMs and their TPP customers to expend substantial costs in implementing the Proposed Settlements and renegotiating contracts, the AWP benchmark will change yet again as competitors to FDB and Medi-Span enter the market. Does that mean that PBMs as well as their TPP customers have to alter pricing yet again?

B. The Timing of the Proposed Settlements Is Unrealistic and Uncertain

The Proposed Settlements by their terms are scheduled to go into effect no later than 60 days from their "effective dates." Settlement and Release at (A), Doc. #120, at 19. But PBMs, as well as their TPP customers, may not know until the day such a change happens. As explained above, the AWP rollback is likely to require pricing adjustments and renegotiations for thousands of contracts that rely on AWP as a baseline. This is not simply a "flip of the switch" maneuver. Sixty days or less is an impossible deadline for implementing and communicating to customers the implications of a massive pricing overhaul such as this, much less for engaging in thousands of contractual renegotiations. Moreover, there is a bizarre timing discrepancy between

[14] Thus, the FDB Settlement allows FDB the option to continue or resume its publishing if any competitor "is or becomes engaged in the business of publishing or disseminating an electronically integrateable [sic] BBAWP field or other substantially similar drug pricing benchmark . . ." Settlement and Release at (A), Doc. #120, at ¶ 3.

the two Settling Defendants that will throw the marketplace into further disarray: FDB is scheduled to discontinue publishing the AWP and BBAWP fields for all pharmaceuticals within 2 years of the effective date of the Agreement, while Medi-Span has 3 years to discontinue. (The Defendants are supposedly meant to use that lengthy period to notify customers of the change-over.) This discrepancy only adds to the uncertainty surrounding the Proposed Settlements.

Still more confusion is likely to result because appeals by Consumer or TPP Class members – including members yet to be identified – could delay the Settlements' effective date even further, adding to the difficulties in implementation. *See Devlin v. Scardelletti*, 536 U.S. 1 (2002) (establishing that non-named class members who object in a timely manner to approval of a settlement at a fairness hearing can bring an appeal without first intervening). As a result, if any of the thousands of individuals or entities included in the Classes here chooses to appeal, the actual implementation date of these Proposed Settlements would become even more uncertain. In fact, there is continuing uncertainty regarding whether the Proposed Settlements will ever be implemented at all, despite the hoops that PBMs have been and will be forced to jump through to ascertain applicability of the Proposed Settlements, as well as specifics regarding contract-by-contract impact.

V. THE PROPOSED SETTLEMENTS PROMISE TO FOMENT ADDITIONAL LITIGATION

PCMA finds disturbing the admission of Plaintiffs' counsel that a key purpose of the Proposed Settlements is to help them – as well as other unknown parties – to make *claims in other lawsuits "involving pharmaceutical pricing and reimbursement."* FDB Agreement at (B), Doc. # 120 at 22 (emphasis added). A central element of the Proposed Settlements is the establishment of a "Data Room" accessible to Plaintiffs' counsel, as well as to others at the "sole discretion" of Settling Defendants. Given that the Settling Defendants will have insulated

themselves from liability by writing extraordinarily broad releases,[15] it is likely that the Data Room has an ulterior and collateral purpose, namely to collect documents that would be used proactively to prosecute other "pharmaceutical pricing or reimbursement" litigation in the future, including possible litigation against PBMs, as well as retail and mail-order pharmacies. Yet paradoxically those PBMs and pharmacies are the very entities which are either included in Class 2 and meant to be benefited by the Proposed Settlements, or are specifically recognized by all as having no involvement in the Settling Defendants' alleged scheme. *See, e.g.*, Trans. of May 22, 2007 Hearing at 9, 12-14.

Not only would the Proposed Settlements pave the way for fishing-expedition litigation of other matters, but they also would be likely to instigate further litigation of these same matters. For example, given that the TPP Class can pursue only equitable relief, and given the uncertainties surrounding these Proposed Settlements and the difficulties in implementing them, it is possible that a number of TPPs will choose to opt out and sue on their own. It is also possible that individual States, whose claims are excluded from the Proposed Settlements, will sue FDB and Medi-Span as a result of their alleged scheme to change the AWP/WAC markup. As the State Attorneys General who objected to the original settlement terms in a letter dated January 23, 2006 noted, the settlement with FDB tried to impose "an inappropriate and inadequate remedy" and sanctioned "the publishing a fictitious price." Letter of January 23, 2006 to Court, signed by Wisconsin, Illinois, Idaho, Kentucky, Alaska, Iowa and Minnesota Attorneys General. The result of their letter, namely the carving out of States' claims from these lawsuits, does nothing to remedy their concerns, but in fact undermines the repose that is a

[15] These releases even extend to currently unknowable claims brought as a result of the "subsequent discovery or existence of such different or additional facts" that are different from those which class members "know or believe to be true with respect to the claims which are the subject matter of this Agreement." Settlement and Release at (A), Doc. #120, at 28.

natural aim of beneficial settlements and instead may foment future litigation. If, as that letter notes, State Medicaid programs believe they stand to gain from litigation, why would the States not sue individually as well, thus wreaking additional havoc for all entities in the marketplace?

VI. THE SETTLEMENTS MANDATE IMPROPER AND UNNECESSARY PRICING DISCUSSIONS BETWEEN COMPETITORS AND SUPPLIERS

As PCMA noted in its letter to this Court of June 20, 2007, attached hereto as **Exhibit 1**, the difficulties created for PBMs by the Proposed Settlements are further illustrated by an additional, unfortunate provision that purports to require PBMs to participate in highly sensitive pricing discussions with competitors, suppliers, and customers alike – discussions that appear to have no pro-competitive benefits whatsoever. The provision mandates that the multiple entities engaged in the pharmaceutical chain, whether as manufacturers, buyers, or sellers, must participate

> *in a Settlement Court-approved mediation process meant to facilitate the establishment of a sustainable benchmark for pharmaceutical reimbursement.*

Among other concerns raised by such a requirement – were it imposed – is that antitrust regulators may look askance at any plan to allow both buyers and sellers, both horizontal and vertical competitors in the pharmaceutical chain, to engage in sensitive discussions regarding pricing to determine a "sustainable benchmark" that would then be mandated by order of a Federal Court for all of them "for pharmaceutical reimbursement." To do so would invite not only possible Federal action by the FTC or Department of Justice, but also possible follow-up private lawsuits. A Court Order cannot insulate an entity from the strictures of the antitrust laws if it engages in actions prohibited by those laws, including discussion of the most sensitive topic

of all – prices to be charged or to be paid, either directly or indirectly.[16] Nor can a Federal Court compel third parties to have discussions that essentially abrogate the provisions of section 1 of the Sherman Act.

There is, fortunately, no need to engage in such problematic discussions. The marketplace already has made room for myriad measures of pharmaceutical pricing, measures that allow competitors to work with customers to choose alternatives that work for them. Instead of furthering the objectives on which the Complaints are based, this provision seems to impose a one-size-fits-all standard that eventually would undermine free and fair competition in the marketplace rather than make it more competitive. Such a mandate is especially inappropriate as applied to PBMs, which relied in good faith on AWP figures as reported by the Settling Defendants, and are recognized by this Court as parties with no knowledge of "the collusion to increase the WAC/AWP markup," Order of Aug. 27, 2007, Doc. #317, at 19, and certainly nowhere accused of having engaged in any manner in the alleged RICO conspiracy.

CONCLUSION

Critically for PBMs, instead of the certainty and clarity that settlements generally impose, these Proposed Settlements with FDB and Medi-Span create both uncertainty for the entire pharmaceutical marketplace as well as more problems for the alleged beneficiary Class members than they solve. While eliminating the longstanding use of AWP as a benchmark for PBM contracts both with their customers (the TPPs) as well as with their pharmacist networks, they force PBMs and TPPs to engage in complex and expensive preparation for their effective dates,

[16] *See Conrac Corp. v. AT&T*, 546 F. Supp. 429, 433 (S.D.N.Y. 1982) ("Conrac points out correctly that agreements in settlements of litigation that set prices or expressly divide markets cannot survive antitrust scrutiny."); *In re Terazosin Hydrocholoride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1309 (S.D. Fla. 2005) ("Indeed, there is nothing magical about a settlement that immunizes an agreement that may otherwise violate the antitrust laws.").

all under a cloud of continuing uncertainty regarding exactly when the Proposed Settlements will go into effect and whether the Settling Defendants will use the broad discretion bestowed on them by the Proposed Settlements to blow them up now or at some future date. Economic markets do not work well with uncertainty hanging over them, as the Court's expert has pointed out.[17]

Rather than redressing the alleged market imbalances caused by Defendants' blatant misrepresentations regarding AWP, which the markets have already largely corrected successfully, the Proposed Settlements impose a Draconian solution that makes the problem worse by creating a new fictitious pricing scheme that already has imposed – and will continue to impose – huge transactional costs on PBMs and retailers as well as subject them to the future threat of litigation rather than the repose that settlements normally attempt to achieve. Further, they contain at least one patently unacceptable mandate – the mediation provision requiring discussions regarding a "sustainable benchmark" – that PBMs believe is both unnecessary and could create serious legal liability with entities attempting to comply with a Court Order.

Nor would consumers who have paid for prescription drugs emerge as winners from these Proposed Settlements, given the narrow and arbitrary group of consumers who will benefit, and the complete absence of settlement monies to reimburse any of them who are truly out-of-pocket as a result of the Settling Defendants' alleged scheme.

In sum, PBMs have relied in good faith on AWP over the course of many years, and believe that any drug pricing benchmark (whether AMP, WAC, or other measure) should be flexible enough to foster the enormous variety and contractual diversity that now exists in the PBM industry, diversity that allows what the FTC calls "vigorous competition" in the PBM

[17] Report of Ernst R. Berndt, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, U.S. District Court, District of Mass., MDL No. 1456, Civ Action No. 01-12257-PBS, Feb. 9, 2005, at para. 16.

market sector to flourish. What PBMs cannot condone is a purported conspiracy between industry information specialists who first chose to engage in wrongdoing and violate a fundamental trust, and have now *compounded that egregious behavior* by choosing to enter into disruptive Settlements that benefit themselves alone, while creating disarray and huge additional transactions costs for all of the other entities in the pharmaceutical distribution chain.

PCMA respectfully requests that this Court refuse to finalize these Proposed Settlements, or modify them so as to place their burden where it belongs: on the offending parties rather than on the rest of the industry. In addition, given the enormous implications of the Proposed Settlements for the entire pharmaceutical chain, including pharmacists, PBMs, TPPs, as well as consumers, PCMA respectfully asks the Court to implement its prudent suggestion of appointing an economist to review the Proposed Settlements and the litigation in order to provide an opinion on the proposed solution as well as possible alternatives. PCMA believes such an analysis would reveal that the Proposed Settlements are based on inaccurate and exceedingly simplistic conceptions of the pharmaceutical marketplace and that the rollback they contemplate not only is unnecessary, but compounds many-fold the initial alleged wrongdoing.

Dated: December 20, 2007

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CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2007, I electronically filed the foregoing Amicus Pharmaceutical Care Management Association's Opposition to the Proposed FDB and MEDI-SPAN Settlements with the Clerk of Court using the CM/ECF system which will send notification of such filing(s) to counsel of record.

DATED: December 20, 2007

/s/ John J. Aromando
John J. Aromando, BBO #545648

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

June 20, 2007

Honorable Patti B. Saris
United States District Judge
United States District Court for the District of Massachusetts
1 Courthouse Way
Boston, MA 02210

Re: **New England Carpenters Health Benefits Fund, et al. v. First DataBank, Inc. and McKesson Corporation, Civil Action No. 05-11148-PBS; District Council 37 Health and Security Plan v. Medi-Span, Civil Action No. 07-CV-10988**

Dear Judge Saris:

We are writing on behalf of Pharmaceutical Care Management Association (PCMA) to share our substantial concerns regarding the proposed settlement in the above case proposed by Plaintiffs and Defendants First DataBank ("FDB") and Medi-Span. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. We are writing in anticipation of the preliminary fairness hearing now scheduled for June 21, 2007.

We intend this short letter to be helpful to the Court with regard to the fairness and reasonableness of the Proposed Settlement. In particular, the Settlement as currently structured (1) represents an overreaction to a largely non-existent problem which will impose unnecessary transaction costs on numerous entities, including much of the proposed Private Payor Class (the "Class"); (2) contains an unrealistic and unworkable definition of the Class that would require examination of individual PBM contracts to determine membership; and (3) requires PBMs to engage in unnecessary and potentially inappropriate pricing discussions with competitors and suppliers.

As this Court correctly noted at the May 22nd hearing, the Proposed Settlement here is "very unusual." (Trans. at p. 58) Plaintiffs allege a RICO "conspiracy" that they claim has cost 11,000 third party-payors billions of dollars; yet, for no monetary payment whatsoever by the defendants, the Proposed Settlement would grant FDB – and now Defendant Medi-Span -- a general release of the very claims that are at the core of this alleged fraudulent scheme. In short, the Proposed Settlement requires nothing of the principal alleged conspirators, FDB and Medispan. Instead, the Proposed Settlement appears designed to make public policy and "fix" a problem that market participants have already addressed.

* * *

1. The Proposed Settlement Attempts to Address an Issue that Has Been Largely Dealt With by the Marketplace

Thus, Plaintiffs make the simplistic, but incorrect, assumption that a "static" marketplace over the seven years since the Class Period began on January 1, 2000, failed to take account of alleged higher AWPs. Far from static, the PBM industry and its clients, the Class members, are highly sophisticated, operating in a competitive and dynamic marketplace.[1] Price changes – let alone the significant price changes alleged by the Plaintiffs -- do not go unnoticed or unaddressed by PBM clients, which include health benefit plans, self-insured employers, third-party administrators (TPA), and union-sponsored plans. No less an authority than the Federal Trade Commission has noted on many occasions the industry's "highly competitive" nature, with PBMs competing on both price dimensions (such as the reimbursement rate and dispensing fee paid to pharmacies, rebates paid to plan sponsors and mail order pricing), as well as non-price dimensions, such as plan design, how extensive the PBM's retail network is, and the availability and extent of mail order services. Federal Trade Commission and U.S. Department of Justice, "Improving Health Care: A Dose of Competition," ch. 7, at 15 (July 2004), ("Healthcare Report"), available at www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf. [2]

In this competitive marketplace, PBM clients – many in the Class -- are well aware of their numerous choices among the 40 to 50 PBMs operating in the country today, as they search for lower prescription drugs prices and additional services for plan members. Those sophisticated clients, often advised by consultants, possess an ongoing ability to bargain for contractual provisions regarding various discounts, rebates, fees and reimbursement formulas available. Although PBM contracts sometimes have a term of as long as three years, they often contain terms that allow pricing factors to be adjusted during that period; in any event, as a practical matter, clients are able to demand pricing concessions in response to market developments at any time. The result is that, over the Class Period, PBMs have been able to provide – and Class members have benefited from – increasingly deeper discounts in the mail service and retail channels, lower administrative and dispensing fees, and higher levels of manufacturer rebate-sharing. It is a fallacy to assume that AWP increases occurring in 2002 and 2003 have not been substantially, if not entirely, offset by marketplace forces in this highly competitive setting.

In short, PBM clients and other industry participants focus intently on prescription drug pricing, and adjust their contract terms accordingly. In this way, the marketplace for PBM services has already reacted to the changes effected over the course of the Class Period. As this Court recognized during the May 22, 2007, hearing on Plaintiffs' Motion for Class Certification

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[1] During the seven-year Class Period, in fact, the highly competitive PBM industry has been extremely successful in keeping costs down for their clients *in the midst of Plaintiffs' alleged conspiracy to inflate drug prices*. As found in a recent Federal study, prescription drug-spending slowed to its lowest growth rate in 2005 in over a decade, with the 5.8% prescription–drug growth rate in 2005 representing a 33% reduction from the 2004 growth rate of 8.6%. The study credits some of the tools employed by PBMs, including tiered co-payment benefit plans and formularies, a continued shift to the use of generic drugs, and continued strong growth in mail-service pharmacies. Catlin, A., Cowan, C., et al., "National Health Spending in 2005: The Slowdown Continues," Health Affairs 142 (Jan. 2007). The authors are all with the Centers for Medicare and Medicaid Services, Office of the Actuary.

[2] This Court's own expert report from Dr. Ernst R. Berndt in the underlying AWP case also challenged the assumption that PBM competition was inadequate, and highlighted the "vigorous" competition among PBMs for the business of third-party payors. Report at 112-113.

in this matter, "as we all know, the PBMs and the consulting contracts all give a huge amount of knowledge and leverage to do push back. So within a year or two of the bump-up of the price, you've already seen adjustments." Transcript of May 22, 2007 Hearing, p.8, lines 6-10. Five years later, the fact of the increase in WAC to AWP spread has inevitably been part of contract negotiations between PBMs and their clients, as well as among other market participants, since that time. The increase has, in short, been bargained away.

While failing to remedy any existing injury or harm, the Proposed Settlement will only lead to yet another round of contract and pricing re-negotiations among marketplace participants – this time in response to the arbitrary and across-the-board price change effected by the Proposed Settlement. And with one of two results: (1) either the contract and pricing re-negotiations will be protracted and costly, with PBMs and retail pharmacies – who are not alleged to have participated in the alleged conspiracy – bearing the brunt of the costs of the reduction in the WAC to AWP spread; or (2) the re-negotiations will be relatively efficient, perhaps because existing contracts may allow for pricing modifications in response to an event like the Proposed Settlement, with class members receiving little to no benefit from the Proposed Settlement as a consequence. Either way, what is assured is that, while the Defendants – and alleged wrongdoers in the case – will pay nothing under the terms of this Proposed Settlement, industry participants who have done nothing wrong, who relied in good faith on AWP as a valid pricing benchmark in many of their contracts, and who have long since re-negotiated their contracts in response to the pricing changes that occurred in 2002 and 2003, will be forced to bear unnecessary transaction costs reacting to the Proposed Settlement. Such a result makes no sense.

2. Contract-by-Contract Review is Required to Determine Which PBM Contracts are Included in the Proposed Settlement Class

The Plaintiffs have demonstrated their misunderstanding of the PBM industry in defining the Class to include only those PBMs which are either "the fiduciary of the Third Party Payors" or which "by contract assumed, in whole or in part, the insurance risk of that prescription pharmaceutical benefit." (Updated Order Granting Preliminary Approval, dated June 6, 2007.)

Under this proposed definition, an individual PBM cannot simply be included or excluded as a whole from the Class. Rather, whether a particular PBM is within the scope of the new PBM carve-out depends on a relationship-by-relationship review of *every PBM contract with every client*. Thus, PBMs are not normally deemed "fiduciaries" for their external customers,[3] but in their role as plan sponsors are "fiduciaries" for their own employee benefit plans, including for administration of the prescription drug benefit. They can also in certain cases assume limited "fiduciary" responsibilities (for claims administration) by contract for a particular customer.[4]

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[3] See *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005).

[4] We are assuming that Plaintiffs intend to define "fiduciary" consistently with the Employee Retirement Income Security Act (ERISA), which requires exercise of "any discretionary authority or discretionary control respecting management of such plan. .." 29 U.S.C. § 1002(21)(A).

Finally, since both health insurers and retail pharmacies are considered Class members without the exceptions created for PBMs, the result will be that a parent health insurer that has a subsidiary or affiliated PBM will be considered a member of the class but the affiliated PBM may not be except as to certain contracts. Thus, a given health insurer itself may be included [5] but not its subsidiary PBM, unless for particular contracts that PBM meets the criteria specified in the Settlement, namely acting as a "fiduciary" or "assum[ing] the insurance risk." Since the definition makes no distinction between risk-bearing and non-risk bearing health insurance contracts, the result will be to include TPAs which receive administrative fees for performing services to a benefit plan without bearing any "insurance risk."

In sum, in order to determine whether its contracts are within the scope of the proposed settlement class, each PBM must engage in a contract-by-contract determination as to whether it is included in the proposed Class with respect to particular contracts. That determination may be cumbersome and costly; adding additional concerns regarding the burden imposed by what PBMs believe is an unnecessary and counter-productive Settlement.

3. The Proposed Settlement Inappropriately Mandates that PBMs Engage in Court-Ordered Pricing Discussions with Competitors and Suppliers

The difficulties created for PBMs by the Proposed Settlement are further illustrated by an additional provision in the document which purports to require PBMs to participate in highly sensitive pricing discussions with competitors, suppliers, and customers alike. That provision, in section (5), entitled "Mediation," asks this Court to order the multiple entities engaged in the pharmaceutical chain, whether as manufacturers, buyers, or sellers, to participate:

> *in a Settlement Court-approved mediation process meant to facilitate the establishment of a sustainable benchmark for pharmaceutical reimbursement.*

In essence, this provision seeks to transform this Court into a regulator and imposes a one-size-fits all standard that would make the marketplace less rather than more competitive. It is especially inappropriate as applied to PBMs, which relied in good faith on the AWPs as reported by Defendant FDB and other publishers, and are nowhere alleged to have engaged in any manner in the claimed RICO conspiracy. The PBM industry is as successful as it is in lowering prices of pharmaceuticals because it bargains aggressively with both pharmaceutical manufacturers of brand-name and generic drugs as well as with retail pharmacy networks for distribution of those drugs. The marketplace already has made room for myriad measures of pharmaceutical pricing, measures which allow the many competitors to work with customers to choose measures and alternatives that work for them.

* * *

PCMA believes that any drug price benchmark, whether AWP, AMP, WAC or any other measure, should be both an accurate reflection of pharmaceutical sales transactions, as well as

[5] This analysis is equally applicable to health insurers which contract on an "administrative services only" basis, assuming no pricing risk, as is often the case with self-insured customers.

broad enough to protect the highly individualized nature of drug price negotiations between both PBMs and their customers as well as between PBMs and pharmaceutical manufacturers. We also believe that benchmark should be flexible enough to foster the enormous variety and contractual diversity that now exists in the PBM industry, thus allowing what the FTC terms "vigorous competition" in the PBM market sector to flourish. This Proposed Settlement meets none of those tests, and instead seriously disrupts the industry while imposing unjustifiable costs and burdens on both PBMs and their clients – the class members – who are not alleged to have participated in the alleged unlawful conduct.

We thank the Court for considering our comments.

Respectfully,

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